§ 105.4 Termination of licenses and permits for inactivity.

- (a) If a biological product has not been prepared by a licensee, or imported by a permittee for a period of five years or more, the Administrator may require the licensee to show intent to resume production, or the permittee to show intent to resume importation, within six months of notification. If the licensee does not resume preparation, or the permittee does not resume importation, within six months of notification, or within a mutually agreeable period, the product license, or permit, may be terminated by the Administrator.
- (b) When a license or permit is terminated, the licensee or permittee shall continue to be subject to applicable records provisions of § 116.8.
- 10. In 9 CFR part 116, the heading for the part would be revised to read as follows:

PART 116—RECORDS AND REPORTS

11. The authority citation for part 116 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

12. In § 116.1, paragraphs (a), (b) and (c) would be redesignated as paragraphs (a)(1), (a)(2), and (a)(3), respectively; redesignated paragraph (a)(1) would be revised; the introductory paragraph would be designated as paragraph (a) and would be revised; and new paragraphs (b) and (c) would be added to read as follows:

§ 116.1 Applicability and general considerations.

- (a) Each licensee, permittee, and foreign manufacturer of biological products imported into the United States shall maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the activities within such establishment. Such records shall include, but shall not be limited to, the items enumerated in this part.
- (1) Records shall be made concurrently with the performance of successive steps in the development and preparation of biological products, including new products under development. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any gain or loss of product from the beginning to the end of product preparation.

* * * * *

- (b) In the case of imported products, each permittee shall maintain at the permittee's place of business detailed and accurate records that are relevant to each imported product and that include, but are not limited to, importation documents, sampling records, tests summaries, shipping records, and inventory and disposition records as required in § 116.2.
- (c) When authorized by the Administrator, the licensee, permittee, or foreign manufacturer may maintain and retain records required under part 116 at an alternative location. Such authorization shall be confirmed by the filing of an addendum to the plot plan legend. The addendum shall list the location of the records and the condition of their storage and shall permit the inspection of the records by APHIS inspectors, or foreign inspectors acting on behalf of APHIS.

(Approved by the Office of Management and Budget under control number 0579–0013)

§§ 116.2, 116.3, 116.4, and 116.6 [Amended]

- 13. At the end of §§ 116.2, 116.3, 116.4, and 116.6, the reference to OMB control number "0579–0059" would be removed and the number "0579–0013" would be added in its place.
- 14. Section 116.5 would be revised to read as follows:

§116.5 Reports.

- (a) When required by the Administrator, reports containing accurate and complete information concerning biological products, including but not limited to, product development and preparation, consumer reports, and market suspensions and recalls, shall be prepared and submitted to the Animal and Plant Health Inspection Service by the licensee, permittee, or foreign manufacturer whose products are being imported or offered for importation. Unless otherwise authorized by the Administrator, records necessary to make such reports shall be maintained in each establishment.
- (b) If, at any time, consumer reports concerning the use of products raise questions regarding purity, safety, potency, or efficacy of the products; or a biological product appears to be unsatisfactory or is found to have been prepared, tested, or distributed in violation of the Virus-Serum-Toxin Act or the regulations; the licensee, permittee, or foreign manufacturer shall immediately report the circumstances and the action taken, if any, to the Animal and Plant Health Inspection Service.

(Approved by the Office of Management and Budget under control number 0579–0013)

15. In § 116.7, the second sentence would be revised to read as follows:

§116.7 Test records.

- * * * Summaries of such tests shall be prepared from such records and submitted to the Animal and Plant Health Inspection Service using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial. * * *
- 16. Section 116.8 would be revised to read as follows:

§ 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after the expiration date of a product, or for such longer period as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

Done in Washington, DC, this 28th day of February 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-5406 Filed 3-3-95; 8:45 am] BILLING CODE 3410-34-M

9 CFR Parts 102 and 114

[Docket No. 93-136-1]

Viruses, Serums, Toxins, and Analogous Products; State-Federal Licensure of Veterinary Biologics

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations concerning State-Federal licensing of veterinary biological products. The effect of the amendment would be that a Federally licensed establishment would not be allowed to produce the same veterinary biological product under both a State and Federal product license. Autogenous biologics would not be subject to the same requirement, in that a Federally licensed establishment could hold both State and Federal product licenses for autogenous biologics, but must choose to produce each specific serial of such biologic